CHANGE OF ADDRESS

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REMARKS

Applicants have carefully considered the Examiner's Non-Final Office Action, and respectfully request reconsideration of this Application in view of the above amendments and the following remarks.

Pending in this Application are Claims 1, 4-6, 8-12, 15-20, 36 and 39. Claims 1 and 5 are currently amended.

I. SPECIFICATION

The Examiner has found that the brief descriptions of Figures 2(a), 2(b), 2(c), and 2(d) are lacking in the Specification, and has therefore requested appropriate correction.

Applicants have amended the brief description of Figure 2, from page 3, line 32, to page 4, line 6, of the Specification as follows:

~~"Figure 2. Box plots of saposin concentrations in plasma from control and LSD-affected individuals. Saposin concentrations were determined by using 0.25-2µl plasma samples. N= number of samples used in each group. The line within the box is the median level, shaded areas below and above the median represent the 25th and 75th centiles, respectively, and bars represent the range. O depicts the outliers, and * denotes extreme outliers. Galact = galactosialidosis; GM 1 = GM 1 gangliosidosis; Mann = α-Mannosidosis; MLD = metachromatic leukodystrophy; MSD = Multiple Sulphatase Deficiency; NCL = Neuronal Ceroid Lipofuscinosis; N-P = Niemann-Pick disease; SAS = Sialic Acid Storage disease; TSD = Tay-Sachs disease.~~

Figure 2(a). Box plot of saposin A concentrations in plasma from control and LSD-affected individuals. Saposin concentrations were determined by using 0.25-2µl plasma samples. N= number of samples used in each group. The line within the box is the median level, shaded areas below and above the median represent the 25th and 75th centiles, respectively, and bars represent the range. O depicts the outliers, and * denotes extreme outliers. Galact = galactosialidosis; GM 1 = GM 1 gangliosidosis; Mann = α-Mannosidosis; MLD = metachromatic leukodystrophy; MSD = Multiple Sulphatase Deficiency; NCL = Neuronal Ceroid Lipofuscinosis; N-P = Niemann-Pick disease; SAS = Sialic Acid Storage disease; TSD = Tay-Sachs disease.

Figure 2(b). Box plot of saposin B concentrations in plasma from control and LSD-affected individuals. Saposin concentrations were determined by using 0.25-2µl plasma samples. N= number of samples used in each group. The line within the box is the median level, shaded areas below and above the median represent the 25th and 75th centiles, respectively, and bars represent the range. O depicts the outliers, and * denotes extreme outliers. Galact = galactosialidosis; GM 1 = GM 1 gangliosidosis; Mann = α-Mannosidosis; MLD = metachromatic leukodystrophy; MSD = Multiple Sulphatase Deficiency; NCL = Neuronal Ceroid Lipofuscinosis; N-P = Niemann-Pick disease; SAS = Sialic Acid Storage disease; TSD = Tay-Sachs disease.

Figure 2(c). Box plot of saposin C concentrations in plasma from control and LSD-affected individuals. Saposin concentrations were determined by using 0.25-2µl plasma samples. N= number of samples used in each group. The line within the box is the

median level, shaded areas below and above the median represent the 25th and 75th centiles, respectively, and bars represent the range. O depicts the outliers, and * denotes extreme outliers. Galact = galactosialidosis; GM 1 = GM 1 gangliosidosis; Mann = α-Mannosidosis; MLD = metachromatic leukodystrophy; MSD = Multiple Sulphatase Deficiency; NCL = Neuronal Ceroid Lipofuscinosis; N-P = Niemann-Pick disease; SAS = Sialic Acid Storage disease; TSD = Tay-Sachs disease.

Figure 2(d). Box plot of saposin D concentrations in plasma from control and LSD-affected individuals. Saposin concentrations were determined by using 0.25-2μl plasma samples. N= number of samples used in each group. The line within the box is the median level, shaded areas below and above the median represent the 25th and 75th centiles, respectively, and bars represent the range. O depicts the outliers, and * denotes extreme outliers. Galact = galactosialidosis; GM 1 = GM 1 gangliosidosis; Mann = α-Mannosidosis; MLD = metachromatic leukodystrophy; MSD = Multiple Sulphatase Deficiency; NCL = Neuronal Ceroid Lipofuscinosis; N-P = Niemann-Pick disease; SAS = Sialic Acid Storage disease; TSD = Tay-Sachs disease."

CLAIM REJECTIONS – 35 USC §112

1. Claims 1, 4-6, 8-9, 11, 12, 15-20 and 26 stand rejected under 35 USC §112, first paragraph, on the grounds that they are not enabled by the Specification. The Examiner has stated that the Specification of the current application supports practicing the invention in plasma, serum, and whole blood sample. However, the Examiner is of the opinion that there is insufficient support for practicing the invention in urine or amniotic fluid. The Examiner bases her argument on the statement that there is no disclosure in the Specification that the levels of saposins were measured in urine or amniotic fluid samples.

In response, Applicants have amended Claims 1 and 5 to remove references to urine or amniotic fluid samples. This also removes indirect reference to urine or amniotic fluid in dependent Claims 4, 8, 9, 11, 12, 15, 16, 17, 18, 19, and 20. Claim 26 has been withdrawn as part of a non-elected invention, and may have been listed accidentally. Applicants submit

that these amendments cause Claims 1, 4, 5, 8, 9, 11, 12, 15, 16, 17, 18, 19, and 20 to be in condition for allowance.

2. Claims 1, 4-6, 8-12, 15-17, 19, 26, and 39 have been rejected under 35 USC §112, first paragraph, on the grounds that the Specification, while being enabling for diagnosing or monitoring cystinosis, Fabry's disease, Niemann-Pick disease, Pompe's disease and Wolman disease, does not reasonably provide enablement for diagnosing or monitoring the genus of lysosomal storage disorders (LSDs).

In response, Applicants have amended the claims to refer specifically to the LSDs cited in Table 2. Table 2 teaches values determined experimentally for Saposins A, B, C, and D in several LSDs, and one of skill in the art would be able to use this Table to determine whether a difference exists between a given saposin and an LSD and carry out the method taught in the Specification. Specifically, one of skill in the art could read on page 13, line 25, of the Specification that "The above diagnostic tests work by comparing a measured level of analyte in a patient with a baseline level determined in a control population of patients unaffected by a lysosomal storage disorder. A significant departure between the measured level in a patient and baseline levels in unaffected persons signals a positive outcome of the diagnostic test. A departure is considered significant if the measured value falls outside the range typically observed in unaffected individuals due to inherent variation between individuals and experimental error."

This would give a clear demonstration of how to use the information disclosed in Table 2 to carry out the claimed method in patients with the LSDs listed in Table 2.

On the basis of the above arguments, Applicants submit that Claim 1, and dependent Claims 4-6, 8-12, 15-17, and 19 are in condition for allowance. Claims 26 and 39 have been withdrawn as part of a non-elected invention, and may have been listed unintentionally.

3. The Examiner has also made a new rejection of Claims 1, 4-6, 8-9, 11, 12, 15-20, and 26 under 35 USC §112, first paragraph, as failing to comply with the written description requirement. The Examiner states that there is insufficient demonstration that the level of

saposins in urine or amniotic fluid would correlate with the diagnosis of any of the many types of lysosomal storage disorder.

Applicants respectfully submit that the amendments to Claims 1 and 5 described above remove reference to urine and amniotic fluid, thereby removing the basis for this rejection. Claims 1 and 5, as well as dependent Claims 4, 8, 9, 11, 12, 15, 16, 17, 18, 19, and 20 are therefore in condition for allowance.

4. Claims 1, 4-6, 8-12, 15-20, 26, and 39 stand rejected under 35 USC §112, first paragraph on the grounds that they do not comply with the written description requirement. The Examiner states that they contain subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the invention at the time the application was filed. The Examiner further states that since there are many types of lysosomal storage disorders, there may be a strong correlation between the level of a saposin and one type and not between the same saposin and another type.

Applicants submit that this rejection is overcome by the amendments to Claim 1 described above. Claim 1, as amended, recites a method which is fully supported by the Specification in such a way as to demonstrate that the inventor what in possession of the claimed material at the time the application was filed. Claim 1, as well as dependent Claims 4-6, 8-12, 15-17, and 19 are therefore in condition for allowance.

II. CONCLUSIONS

Applicants respectfully submit that, in light of the foregoing Amendment and comments, Claims 1, 4-6, 8-12, 15-20, 36, and 39 are all in condition for allowance. A Notice of Allowance is therefore requested for all claims. If the Examiner has any other matters which pertain to this Application, the Examiner is encouraged to contact the undersigned to resolve these matters by Examiner's Amendment where possible.

Respectfully submitted,

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